NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

DUSA PHARMACEUTICALS, INC., and SIRIUS LABORATORIES, INC.,	:	Civil Action No. 06-1843 (SRC)
Plaintiffs,	:	**OPINION**
v.	:	
RIVER'S EDGE PHARMACEUTICALS, LLC,	:	
Defendant.	:	

CHESLER, District Judge

This matter comes before the Court on the motion by Defendant River's Edge Pharmaceuticals, LLC ("River's Edge") to dissolve the preliminary injunction issued by this Court on May 16, 2006 (docket item # 166). River's Edge contends that changed circumstances warrant the Court's review of new evidence concerning the validity and infringement of the subject patent. Plaintiffs DUSA Pharmaceuticals, Inc. and Sirius Laboratories, Inc., a wholly-owned subsidiary of DUSA Pharmaceuticals, Inc., (hereinafter, collectively, "DUSA"), have opposed this motion. The Court held oral argument on the motion on February 26, 2007. It has considered the arguments presented in the parties' written submissions and in oral argument. For the reasons expressed below, the Court grants the motion by River's Edge.

I. BACKGROUND

This patent infringement action concerns U.S. Patent No. 6,979,468 ("the '468 Patent"), which is directed to an oral pharmaceutical preparation for the treatment of inflammatory skin disorders. The preparation comprises nicotinamide in an immediate release form and zinc in a sustained release form. The '468 Patent contains 16 claims and uses the term "sustained release form." The single independent claim is claim 1, which recites:

> An oral pharmaceutical preparation in dosage unit form adapted for administration for the treatment of inflammatory skin disorders, comprising, per dosage unit, at least 250 mg of nicotinamide in an immediate release form, and an amount of zinc in sustained release form, said amount of zinc being sufficient to provide an enhanced anti-inflammatory effect, in a vehicle pharmaceutically acceptable for oral administration.

Plaintiff DUSA owns the '468 patent.[1] It markets and sells a product known as Nicomide®, which it asserts practices the '468 patent. On or about March 27, 2006, Defendant River's Edge began marketing its product, NIC 750, which it listed in the National Drug Data File[2] as an equivalent substitute for DUSA's prescription Nicomide® product.

On or about April 21, 2006, DUSA initiated this lawsuit and filed a motion for a preliminary injunction to enjoin River's Edge from manufacturing, selling and/or importing the allegedly infringing NIC 750 product and any equivalent product. The Court held oral argument

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[1] The '468 Patent was issued to the inventor, Frank Pollard, on December 27, 2005. It was initially assigned to Sirius Laboratories, and later assigned to DUSA after DUSA acquired Sirius Laboratories on or about March 10, 2006.

[2] The Complaint describes the National Drug Data File as "a resource regularly consulted by physicians, pharmacists, and clinicians to identify potential substitute equivalents of branded pharmaceuticals." (Complaint, ¶ 19.)

on that motion on May 5, 2006. Applying the standard for granting a preliminary injunction, and finding, among other things, that DUSA was likely to succeed on the merits of this patent infringement suit, the Court granted DUSA's motion by Order of May 12, 2006. River's Edge subsequently filed a motion to lift the injunction, as a cross-motion to DUSA's motion to stay this action. On September 11, 2006, the Court denied the cross-motion on procedural grounds as improper pursuant to Local Civil Rule 7.1(h).

In opposition to River's Edge's cross-motion for relief from the preliminary injunction, DUSA had submitted the September 1, 2006 Declaration of Robert. O. Williams (hereinafter, "Williams Declaration"), a pharmaceutics professor at the University of Texas, College of Pharmacy, proffered by DUSA as an expert in pharmaceutical formulation and the use of excipients[3] in formulating immediate release and sustained release druge dosage forms. (Williams Decl., 9/1/06, ¶¶ 1, 4.) Insofar as it is relevant to the instant motion, the Williams Declaration explains:

> A person skilled in the art would easily understand the meaning of the term "sustained release form" as it is used in the '468 patent. Specifically, this term means, a dosage form that is formulated to achieve rate-controlled delivery, so that the active ingredient is made available over an extended period of time. Further, the '468 patent, specification and prosecution history make clear the rate of release for the sustained release form of zinc is a constant rate of release.

(Id., ¶ 23.)

[3] An excipient is defined as "any more or less inert substance added to a prescription in order to confer a suitable consistency or form to the drug; called also *vehicle*." Dorland's Illustrated Medical Dictionary, 652, (30th ed., 2003).

In the meantime, River's Edge filed a Request for *Inter Partes* Reexamination of the '468 Patent with the United States Patent and Trademark Office ("PTO") on May 1, 2006. On November 22, 2006, the PTO granted the request for reexamination and issued an Office Action rejecting all 16 claims of the '468 Patent on grounds of obviousness and/or anticipation. (Stolbach Cert., 12/7/06, Ex. 1 and 2.)

River's Edge now seeks the dissolution of the preliminary injunction based on changed circumstances that raise a substantial question as to the patent's validity and the likelihood that DUSA will be able to prove that River's Edge has infringed the '468 patent.

II. LEGAL ANALYSIS

In its discretion, this Court may dissolve a preliminary injunction. Sprint v. Comm. Co. L.P. v. CAT Comm. Int'l, 335 F.3d 235, 241 (3d Cir. 2003). For the Court to grant this relief, the movant must demonstrate that "changed circumstances warrant the discontinuation of the order." Id. at 242 (quoting Twp. of Franklin Sewerage Auth. v. Middlesex County Utils. Auth., 787 F.2d 117, 121 (3d Cir. 1986)). The Third Circuit has reasoned that requiring a movant to demonstrate changed circumstances prevents constant challenges to an injunction and relitigation of arguments already considered by the court. Id.

This Court finds that River's Edge has demonstrated two changed circumstances that justify the dissolution of the preliminary injunction: (1) the PTO's decision to reexamine the '468 Patent and its accompanying intial Office Action of November 22, 2006 rejecting all 16 of the claims in the '468 Patent and (2) DUSA's definition of the term "substantial release form" through the Williams Declaration. The Court, of course, has considered these changed

circumstances against the backdrop of the standard for granting a preliminary injunction. It is well-established that an essential element of a preliminary injunction application is demonstration of likelihood of success on the merits. Gillette Co. v. Energizer Holdings, Inc., 405 F3d 1367, 1370 (Fed. Cir. 2005); Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350 (Fed. Cir. 2001). To make this showing on a claim of patent infringement, a plaintiff must establish that, in light of the presumptions and burdens applicable to trial on the merits, (1) it will likely prove that the defendant infringed the patent and (2) its infringement claim will likely withstand the defendant's challenges to validity. Genentech, Inc. v. Novo Nordisk, A/S, 108 F.3d 1361, 1364 (Fed. Cir. 1997). However, if the defendant "raises a substantial question concerning either infringement or validity, i.e., asserts an infringement or validity defense that the patentee cannot prove 'lacks substantial merit,' the preliminary injunction should not issue." Amazon.com, Inc., 239 F.3d at 1350-51 (citing Genentech, 108 F.3d at 1364). In this case, changed circumstances have deprived DUSA of its ability to prove likelihood of success on the merits.

First, the PTO Office Action rejecting all of the claims of the '468 Patent on grounds of anticipation and/or obviousness raises a substantial question as to the validity of the '468 Patent. The Court recognizes that a patent is entitled to a presumption of validity. 35 U.S.C.A. § 282. However, DUSA, as the party seeking a preliminary injunction, must demonstrate that its infringement claims will likely withstand the validity challenges presented by River's Edge. Amazaon.com, 239 F.3d at 1351; Oakley, Inc. v. Sunglass Hut Int'l, 316 F.3d 1331, 1339-40 (2003). The Federal Circuit has held that a validity challenge at the preliminary injunction stage may raise a substantial question of invalidity on a lesser burden of proof than is required to

support a judgment of invalidity at trial, that is, less proof than clear and convincing evidence. Amazon.com, 239 F.3d. at 1358-59. While the reexamination order is not dispositive on the issue of validity, the Court does find that "it is probative to the issue of whether [DUSA has] raised a substantial question of validity." Pergo, Inc. v. Faus Group, Inc., 401 F.Supp.2d 515, 524 (E.D.N.C. 2005). In its Decision Granting *Inter Partes* Reexamination, the PTO expressly notes that "a substantial new question of patentability affecting claims 1-16 of [the '468 Patent]" has been raised. (Stolbach Cert., 12/7/06, Ex. 1 at 2.) Moreover, the initial Office Action of November 22, issued contemporaneouly with the order granting reexamination, certainly bears on the merits of the reexamination. 37 C.F.R. § 1.935. The Office Action rejects all the claims of the '468 Patent, and in so doing, provides a detailed explanation of why it considers that various prior art may render the '468 Patent invalid due to obviousness and/or anticipation, under 35 U.S.C. §§ 102(a), (b), and (e), 103(a). (Stolbach Cert., 12/7/06, Ex. 2.) The Court recognizes that the Office Action of November 22 constituted an initial action in connection with the reexamination process and that the PTO's final word on the '468 Patent's validity has not yet issued. DUSA, however, has not shown that the validity question raised by the reexamination order and the Office Action lacks substantial merit. Thus, the Court finds that River's Edge has met its burden of demonstrating a changed circumstance that raises a substantial question of validity with regard to the '468 Patent into question, justifying dissolution of the preliminary injunction.

The Court further finds that the dissolution of the preliminary injunction is equally justified by the second changed circumstance to which River's Edge points in its application, that is, DUSA's statement of what "sustained release form" means in the '468 Patent. The definition

given by DUSA through its proferred expert, Dr. Williams, explains what "sustained release form" generally means and what it means specifically in the context of the '468 Patent. According to the Declaration of Dr. Williams, the term broadly means "rate-controlled delivery." The Court understands from his statement and DUSA's argument to the Court that "sustained release form" encompasses a broad method of delivery that releases the active ingredient over time, which includes but is not limited to release at a constant rate. For purposes of this motion, the Court accepts DUSA's definition of "sustained release form." It is Dr. Williams' specific description of what manner of "rate-controlled delivery" the '468 Patent contemplates that alters the Court's preliminary construction of claim 1 of the '468 patent. Dr. Williams proceeds to explain, in the same paragraph of his Declaration, that "the '468 patent, specification and prosecution history make clear the rate of release for the sustained release form of zinc is a constant rate of release." (Williams Decl., ¶ 23.)

This definition of "sustained release form" as it is used in the '468 Patent is significant because, as the NIC 750 package insert indicates, the accused product delivers zinc in a sustained release. (Stolbach Cert., 12/7/06, Ex. 4 at col. 1.) At the time the Court adjudicated the motion for a preliminary injunction, neither DUSA nor River's Edge had presented the Court with any basis for construing the term "sustained release" as it is used in the '468 Patent in the narrowed manner indicated by the Williams Declaration. Thus, the Court construed claim 1 of the '468 Patent based on the evidence before it and accordingly found that every limitation of the claim had been satisfied by NIC 750, including, significantly, the sustained release of zinc. However, the Court's construction of that claim must now take into consideration the narrowed definition discussed above.

Applying the two-step analysis for determining infringement, the Court finds that DUSA has not demonstrated that it is likely to prevail on the merits of its infringement claim. First, for the limited purpose of adjudicating this motion to dissolve the preliminary injunction, the Court construes the term sustained release as it is used in claim 1 of the '468 patent to mean constant rate of release. Conoco, Inc. v. Energy & Environmental Int'l, L.C., 460 F3d 1349, 1362 (Fed. Cir. 2006) ("the meaning of a claim term . . . may be informed by the surrounding claim language, the specification, the prosecution history, and extrinsic evidence"); Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed Cir. 1998) (en banc) (holding determination of infringement requires court first to construe claim language to ascertain scope and meaning); Sofamor Danek Group, Inc. v. DePuy-Motech, Inc., 74 F.3d 1216, 1221 (Fed. Cir. 1996) (holding court not required to make final conclusions regarding claim construction during preliminary injunction proceedings). DUSA has taken this position through the definition offered by its own own proffered expert, Dr. Williams. He states that the patent language itself, specification and prosecution history make clear that the sustained release of zinc means a constant rate of release. Second, comparing construed claim 1 to NIC 750, the Court finds that DUSA has not demonstrated that the allegedly infringing product falls within the scope of the '468 patent, or, in other words, that it would be likely to prove the "constant rate of release" limitation of the patent is contained in NIC 750. Seal Flex, Inc. v. Athletic Track and Court Const., 172 F.3d 836, 842 (Fed. Cir. 1999) (holding that proving infringement requires the patentee to demonstrate that the accused product meets each claim limitation of the subject patent). DUSA has not presented the Court with any evidence that NIC 750 releases zinc at a

constant rate.[4] In short, the preliminary injunction must be dissolved because the definition offered by Dr. Williams raises a substantial question as to DUSA's ability to prove infringement at trial.

III. CONCLUSION

For the foregoing reasons, the motion by River's Edge will be granted, and the preliminary injunction issued by this Court by Order of May 15, 2006 will be dissolved. An appropriate form of order will be filed together with this Opinion.

s/ Stanley R. Chesler
STANLEY R. CHESLER
United States District Judge

DATED: March 6, 2007

[4] Moreover, DUSA has not adduced any evidence indicating that its product practices the '468 patent under the construction given by its own expert, thereby substantially affecting the equities of the parties and militating against the maintenance of the preliminary injunction.